July 18, 2019

Huvitz Co., Ltd.
% Dave Kim
President
MTech Group
8310 Buffalo Speedway
Houston, TX 77025

Re: K191615
Trade/Device Name: Huvitz Imaging System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: June 10, 2019
Received: June 18, 2019

Dear Dave Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Bradley Cunningham
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191615

Device Name
Huvitz Imaging System
HIS-5000U (10.0M, 5.0M, 1.4M)

Indications for Use *(Describe)*

Huvitz Imaging system (HIS-5000U) is intended for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentation ophthalmic images and videos, acquired from a slit lamp camera through a direct connection to a PC or to multiple PCs via a local network.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date Prepared: 7/12/2019

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Trade Name: Huvitz Imaging System (HIS-5000U)
Common Name: System, Image Management, Ophthalmic.
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class:: Class II
Product Code: NFJ

Predicate Device: Huvitz Imaging System (HIS-5000U), K161829
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class:: Class II
Product Code: NFJ

Device Description: Huvitz Imaging System (HIS-5000U) consists of slit lamp camera (HIS-5000U(10.0M), HIS-5000U(5.0M), HIS-5000U(1.4M)), Communication Cable and Imaging Software (HIS-5000N). It is a digital imaging system with a high resolution digital camera and PC based patient diagnostic data management software intended for controlling digital imaging devices, acceptance, transfer, display, storage and digital processing of ophthalmic images including videos, acquired from a of a slit lamp camera through direct connection or network.

The imaging software (HIS-5000N) supports networking function to share patient information and examination images between multiple PCs existing on the local network or internet via TCP/IP protocol. Also, this version uses MS-SQL server solution as more reliable database, and includes additional HIS Server Management software to support to back up or restore patient

and imaging data. HIS-5000N imaging system software is not able and intended to provide any diagnosis but help the user to view the visible structures of the eye and store the findings.

Indications for Use: Huvitz Imaging system (HIS-5000U) is intended for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentation ophthalmic images and videos, acquired from a slit lamp camera through a direct connection to a PC or to multiple PCs via a local network.

Technological characteristics:

Huvitz Imaging system (HIS-5000U) has been compared to the predicated device. The following attachment shows differences and similarities among the device.

Performance test:

Non-clinical tests:

Performance testing was conducted on the Huvitz Imaging System (HIS-5000U). System and supported instrument testing was completed based on product specifications and hazard effects determined from the risk analysis. The Huvitz Imaging System (HIS-5000U) performed as intended and is deemed substantially equivalent to and comparable to the predicate device.

Also, the following tests have been conducted to validate the performance of Huvitz Imaging System (HIS-5000U).

1) Camera Resolution, 2) Camera Time machine Function, 3) Camera Flicker, 4) Camera Image Capture 5) Saving image file, 6) Adjust Color as per the manufacturer's performance report.

The reasons for selecting the test items 1), 4), 5), 6) are for checking camera functions due to the introduction of a new image sensor.

The reasons for selecting the test items 2), 3) are for checking camera resolution due to the additional functionalities.

Clinical test:

Huvitz Imaging system (HIS-5000U) does not require clinical testing, given the precedent of predicate equipment.

No clinical test has been conducted.

Conclusions: In the performance test report, the performance was evaluated at an equivalent level in tests compared to the predicate device, and the risk is also low because the device is not a treatment device or a diagnostic device. Based on non-clinical tests, the subject device, Huvitz Imaging System (HIS-5000U) introduces no new concern for safety and effectiveness. Therefore it is the sponsor's opinion that Huvitz Imaging System (HIS-5000U) is as safe, as effective, and performs as well as the legally marketed device predicate K161829.

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Attachment

< Comparison Table of Technical Characteristics >

1. Summary of technological differences and similarities

1.1 Technological differences:

- Hardware: image sensor size(1" CMOS), image pixel size(up to 2592 x 2048 pixels), Data transmit speed(5.0 Gbps), Memory capacity (4GB), Graphic Card(On board graphics chip(PCI/PCIe graphics card with DirectDraw supporting DirectX 9.0 0 or Higher)) and Interface(USB 3.0)
- Software: Operating System(Windows 10), software version(updated Ver. 4.04.19A)

1.2 Technological similarities:

- Frame rate, Monitor resolution, storage method, type of images and video format, Ability to control camera systems and exposure parameters, database and functions.

2. Comparison of features and specifications of the predicate devices and subject devices

* New model HIS-5000U(5.0M) is added 5.0M imaging sensor compared with predicate device. Added the model HIS-5000U(5.0M) doesn't affect safety or performance's concern because differences of feature are just about image size, transmit speed, frame rate and interface.

Characteristic	**Predicate Device** Huvitz Imaging System HIS-5000U	**Subject Device** Huvitz Imaging System HIS-5000U
510(k) number	K161829	New
Manufacturer	Huvitz Co.,Ltd	Huvitz Co.,Ltd
Device Name	Huvitz Imaging System HIS-5000U (1.4M, 10.0M)	Huvitz Imaging System HIS-5000U (1.4M, 10.0M, 5.0M)

Characteristic	Predicate Device Huvitz Imaging System HIS-5000U		Subject Device Huvitz Imaging System HIS-5000U		
Indications for Use	Huvitz Imaging system (HIS-5000U) is intended for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentation ophthalmic images and videos, acquired from a slit lamp camera through a direct connection to a PC or to multiple PCs via a local network.		Huvitz Imaging system (HIS-5000U) is intended for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentation ophthalmic images and videos, acquired from a slit lamp camera through a direct connection to a PC or to multiple PCs via a local network.		
Specification	HIS-5000U(1.4M)	HIS-5000U(10.0M)	HIS-5000U(1.4M)	HIS-5000U(10.0M)	HIS-5000U(5.0M)
Image sensor	1/2" CCD	1/2" CMOS	1/2" CCD	1/2" CMOS	1" CMOS
Image size	up to 1280x1024 pixels	up to 3840 x 2748 pixels	up to 1280x1024 pixels	up to 3840 x 2748 pixels	up to 2592 x 2048 pixels
Transmit speed	480Mbps	480Mbps	480Mbps	480Mbps	5.0 Gbps
Frame rate	Maximum 15fps	Maximum 30fps	Maximum 15fps	Maximum 30fps	Maximum 30fps
Memory	2,048MB	2,048MB	2,048MB	2,048MB	4GB
Graphic Card	512MB	512MB	512MB	512MB	On board graphics chip(PCI/PCIe graphics card with DirectDraw support DirectX 9.0 0 or Higher)
Operating System	Window 7	Window 7	Window 7	Window 7	Window 10
Interface	USB 2.0	USB 2.0	USB 2.0	USB 2.0	USB 3.0
Monitor resolution	1920 x 1080	1920 x 1080	1920 x 1080	1920 x 1080	1920 x 1080
How to store patient data	Be comprised of a local database to store patient data and		Be comprised of a local database to store patient data and		

Characteristic	**Predicate Device** Huvitz Imaging System HIS-5000U	**Subject Device** Huvitz Imaging System HIS-5000U
and diagnostic documents	diagnostic documents	diagnostic documents
Type of images and video format	JPEG	JPEG
Ability to control camera systems and exposure parameters like signal gain, exposure time or white balance (by default or an option)	Be capable of controlling supported camera system and exposure parameters like signal gain, exposure time or white balance.	Be capable of controlling supported camera system and exposure parameters like signal gain, exposure time or white balance.
Ability to provide the management, storage and processing and display of patient, diagnostic video and image data	USB Camera has unique power requirement that varies on image resolution and data bandwidth needed to transport image data	USB Camera has unique power requirement that varies on image resolution and data bandwidth needed to transport image data
Type of system that provide a software application (client) to view or modify the stored data in the database (server)	Software should be installed in a computer using an installer file. After the software and camera driver installation, HIS-5000U program can check patient image data and current database information on a local computer.	Software should be installed in a computer using an installer file. After the software and camera driver installation, HIS-5000U program can check patient image data and current database information on a local computer.
Functions to add test notes to medical records	Diagnosis management can add or edit diagnostic information.	Diagnosis management can add or edit diagnostic information.
Function to highlight features in images	User can select a thumbnail image by clicking it, which is highlighted as bright color, and it is able to select several images from different exams of the same patient. The	User can select a thumbnail image by clicking it, which is highlighted as bright color, and it is able to select several images from different exams of the same patient. The

Characteristic	**Predicate Device** Huvitz Imaging System HIS-5000U	**Subject Device** Huvitz Imaging System HIS-5000U
	selections are cleared when the processing on image are completed.	selections are cleared when the processing on image are completed.
Function to enhance image brightness, contrast and sharpness	Provide functions to enhance image brightness, contrast and sharpness.	Provide functions to enhance image brightness, contrast and sharpness.
Function to measure pixels or mm,	Function to measure pixels and mm	Function to measure pixels
Function to search to retrieve medical records lined to a specific patient	All patient data is stored in a database file, and a search function can retrieve patient database transaction history stored in the Database Log File.	All patient data is stored in a database file, and a search function can retrieve patient database transaction history stored in the Database Log File.
Function to export and import data	Include a function to export and import data	Include a function to export and import data
Function to print out the stored data	Can produce printouts of the stored data.	Can produce printouts of the stored data.
Function to compare images by displaying images side by side	Function to compare images by displaying images side by side More than two images can be selected from Thumbnail List for comparison.	Function to compare images by displaying images side by side More than two images can be selected from Thumbnail List for comparison.
Function to connect to LAN and have DICOM interface	Can connect to LAN but No DICOM interface	Can connect to LAN but No DICOM interface
HIS-5000N Software Version	Ver. 2.04.13	Ver. 4.04.19A